

STATEMENT OF BASIS for IMCLONE SYSTEMS LLC

TITLE V OPERATING PERMIT RENEWAL

Program Interest (PI): 36066 / Permit Activity Number: BOP200001

I. FACILITY INFORMATION

ImClone Systems LLC is located at 33 ImClone Dr, Branchburg, Somerset County, NJ 08776 and consists of pharmaceuticals manufacturing facility. The facility is owned by Eli Lilly & Company and is operated by ImClone Systems LLC.

The facility is classified as a major facility based on its potential to emit of 89.1 tons per year of volatile organic compounds and 34.0 tons per year of oxides of nitrogen.

This permit allows individual hazardous air pollutants to be emitted at a rate not to exceed: 0.000176 ton/year of arsenic, 0.000122 tons/year of cadmium, 0.0657 tons/year of formaldehyde, 0.00185 tons/year of nickel. Total HAPs emissions from insignificant sources and/or non-source fugitives are estimated values and are not speciated.

VOC emissions are being corrected to include formaldehyde emissions previously not accounted for. This emission increase is meant to capture emissions already present and no new actual emissions are being generated. As a result, the Department is not revisiting the applicability of State of The Art (N.J.A.C. 7:27-22.35) and Federal New Source Review (40 CFR 52.21-PSD and N.J.A.C. 7:27-18).

II. AREA ATTAINMENT CLASSIFICATION

The Federal Clean Air Act (CAA) sets National Ambient Air Quality Standards (NAAQS) for six common air pollutants. These commonly found air pollutants (also known as "criteria pollutants") are particulate matter, ground-level ozone, carbon monoxide (CO), sulfur dioxide (SO₂), nitrogen dioxide (NO₂), and lead. The US Environmental Protection Agency (USEPA) also classifies areas as "attainment" or "nonattainment" for each criteria pollutant, based on the magnitude of an area's problem. Nonattainment classifications are used to specify what air pollution reduction measures an area must adopt, and when the area must reach attainment. Currently, the entire State of New Jersey is designated as nonattainment for the 8-hour ozone NAAQS. New Jersey is designated attainment for all other pollutants. For nonattainment classification refer to <https://www.epa.gov/green-book/green-book-national-area-and-county-level-multi-pollutant-information>.

III. BACKGROUND AND HISTORY

The equipment that emits air contaminants from this facility include: pharmaceutical processing equipment, natural gas fired boilers, diesel fired emergency generators, and natural gas fired emergency generators.

This permit also incorporates five general operating permit(s) (Activity #s BOP210001, BOP210002, BOP210003, BOP210004 and BOP210005) that the facility obtained for two dual-fuel (natural gas/propane) emergency generators with a heat input rate of 1.54 MMBTU/hr (HHV) each, permitted to operate up to 100 hours per year for testing and maintenance, and three natural gas boilers with a heat input of 1.5 MMBTU/hr (HHV) each. The total increase in facility emissions due to the addition of these new GOPS is 2.06 tons of NO_x, 0.1 tons of VOC, 2.05 tons of CO, and 20,800 tons of CO₂(e) per year.

Table 1 - Operating Permit Revision History (located at the end of this document) provides a summary of all the changes that have been incorporated into the operating permit through seven-day notice changes, administrative amendments, minor modifications, or significant modifications since the approval of the initial operating permit or the most recent renewal thereof. Please refer to the attached explanation sheet for the structure and configuration of conditions of approval, included in the Facility Specific Requirements section of this permit.

A Facility-Wide Risk Assessment was conducted as part of the review of this permit application and health risk was determined to be negligible consistent with NJDEP Technical Manual 1003.

This is a Permit Renewal and includes the following changes:

PM-2.5 emissions limits for U10, U104, U105, U106, U107 and U108 were updated consistent with N.J.A.C. 7:27-22.

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The following equipment has been removed from the permit:

IS7 - Dispensary/Weighing Operations

FG1 - Equipment sanitation using 70% IPA

U1 - Three NG Boilers 24.5 MMBtu/hr, 24.5 MMBtu/hr, 3.5 MMBtu/hr (E100, E101, E1202, PT51)

U4 - 2.4 MMBtu/hr Diesel Emergency Generator (E401, PT4)

U5 - 11 MMBtu/hr diesel emergency generator (E1, PT6)

U6 - 1.27 MMBtu/hr natural gas emergency generator (E2, PT7)

U5006 - 1.2 MMBtu/hr Low pressure boiler (E100001, PT1)

BP1 - Manufacturing in building BB36, and BP3 - Small scale production in BB59/61, (E51, E111, E112, E113, E114, E115, E116, E117, E118, E119, E120, E121, E122, E123, E124, E125, E126, E127, E128, E129, E130, E131, E132, E133, E134, E135, E136, E137, E138, E139, E140, E141, E142, E143, E149, E150, E151, E152, E153, E154, E167, E168, E169, E175, E176, E177, E178, E6101, E6102, E6103, E6104, PT3, PT4, PT5, PT6, PT9, PT12, PT15, PT16, PT17, PT21, PT23, PT24, PT39, PT40, PT42, PT50, PT51, PT52, PT107, PT4001 and PT6003).

Monitoring and recordkeeping requirements for BP2:OS0 - Manufacturing in building BB50, were updated to clarify the required contents of the batch records.

SO2 emissions were updated based on the new N.J.A.C. 7:27-9 sulfur content rules. SO2 emissions from U10, U107 and U108 were removed.

HAPs emissions were updated based on the new permit reporting thresholds in N.J.A.C. 7:27-17. Emissions of 0.0000585 tons/year Arsenic, 0.0000405 tons/year Cadmium, 0.0219 tons/year Formaldehyde and 0.0615 tons/year Nickel were added to U104, U105 and U106. VOC emissions for U104, U105 and U106 were updated to include Formaldehyde; annual VOC emissions were updated from 1.49 tons/year to 1.51 tons/year.

The following GOPs are being incorporated into the permit:

BOP210005: U15 - 1.5MMBtu/hr Natural Gas Only Boiler, E12, PT25

BOP210004: U14 - 1.5MMBtu/hr Natural Gas Only Boiler, E11, PT22

BOP210003: U13 - 1.5MMBtu/hr Natural Gas Only Boiler, E10, PT20

BOP210002: U8 - 1.54MMBtu/hr Natural Gas Emergency Generator, E4, PT18

BOP210001: U12 - 1.54MMBtu/hr Natural Gas Emergency Generator, E9, PT19

The changes made during this permitting action result in allowable annual emissions changes as follows: VOC emissions were reduced from 125 tons/year to 89.0 tons/year, NOx emissions were reduced from 47.1 tons/year to 35.9 tons/year, CO emissions were reduced from 99.7 tons/year to 62.1 tons/year, SO2 emissions were reduced from 2.20 tons/year to 1.82 tons/year, TSP emissions were reduced from 16.6 tons/year to 13.9 tons/year, PM10 emissions were reduced from 16.7 tons/year to 13.9 tons/year, PM-2.5 emissions were updated to 13.9 tons/year, HAPs emissions were updated to 0.07 tons/year.

IV. BASIS FOR MONITORING AND RECORDKEEPING REQUIREMENTS

The facility's operating permit includes monitoring, recordkeeping and reporting requirements that are sufficient to demonstrate the facility's continued compliance with the applicable requirements consistent with the following:

1. Provisions to implement the testing and monitoring requirements of N.J.A.C. 7:27-22.18, the recordkeeping and reporting requirements of N.J.A.C. 7:27-22.19, and all emissions monitoring and analysis procedures or compliance assurance methods required under the applicable requirements, including any procedures and methods promulgated pursuant to 40 CFR 64; and
2. Where the applicable requirement does not require direct periodic monitoring of emissions, the Department requires periodic monitoring of surrogate parameters sufficient to yield reliable data from the relevant time period that are representative of the facility's compliance with the permit.

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For boilers U11, U104, U105, U106, U5006 the facility monitors fuel use as the surrogate for the long-term (TPY) emission limits for VOC, NOx, CO, SO2, TSP, PM-10 and PM-2.5. Surrogate monitoring for the short-term (lb/hr) emission limits for U104, U105, U106 are combustion process adjustment for NOx and CO, and fuel oil sulfur content for SO2.

For emergency generators U10, U107, U108, U1101, U1301, the facility monitors the hours of operation as the surrogate for the long-term (TPY) emission limits for VOC, NOx, CO, SO2, TSP, PM-10 and PM-2.5. Surrogate monitoring for the short-term (lb/hr) emission limits for the diesel engines, U10, U107, U108, U1101, U1301 are the fuel oil sulfur content for SO2.

3. In some cases, direct periodic monitoring of emissions and/or surrogate parameters is not required due to one or more of the following:

- Equipment size and capacity limitations,
- Subject equipment being permitted at the maximum rated capacity,
- There is no specific state or Federal standard that applies to this piece of equipment,
- Not a pollutant of concern for this piece of equipment,
- Agreements with EPA on the frequency of testing and monitoring for combustion sources.

Based on the above criteria, there is no direct or surrogate monitoring for the following pieces of equipment:

E5 (U9), 1.568 MMBtu/hr Natural gas boiler BB 1181; E6001 (U6001), Building BB 59/61 HHW1 Cleaver Brooks boiler burning natural gas; E6002 (U6001), Building BB 59/61 HHW2 Cleaver Brooks boiler burning natural gas

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V. APPLICABLE STATE AND FEDERAL RULES

The facility is subject to New Jersey Air Pollution Control Regulations, codified in N.J.A.C. 7:27-1 through 34, as applicable. A complete text of these regulations is available at:

<http://www.nj.gov/dep/aqm/rules27.html>

The facility is subject to Federal regulations listed below.

| | |
|------------------------|--|
| 40 CFR 60 Subpart A | General Provisions |
| 40 CFR 60 Subpart Dc | Small Industrial-Commercial-Institutional Steam Generating Units |
| 40 CFR 60 Subpart JJJJ | Stationary Spark Ignition Internal Combustion Engines |
| 40 CFR 63 Subpart A | General Provisions |
| 40 CFR 63 Subpart ZZZZ | Stationary Reciprocating Internal Combustion Engines |

The Greenhouse Gas (GHG) emissions from this facility are 114,545 TPY CO₂e and there is no GHG emissions increase. This renewal is not subject to PSD rules at 40 CFR 52.21.

VI. FACILITY'S COMPLIANCE STATUS

The Responsible Official at the facility has certified that the facility currently meets all applicable requirements of the Federal Clean Air Act and the New Jersey Air Pollution Control Act. Based on this certification, the Department's evaluation of the information included in the facility's application, and a review of the facility's compliance status, the Department has concluded that this air pollution control operating permit should be approved.

The facility has submitted a timely and complete application to renew their operating permit and an application shield is in effect.

This operating permit includes a permit shield, pursuant to the provisions of N.J.A.C. 7:27-22.17. A permit shield provides that compliance with the relevant conditions of the operating permit shall be deemed compliance with the specific applicable requirements that are in effect on the date of issuance of the draft operating permit, and which form the basis for the conditions in the operating permit.

Also, prior to the expiration of the five-year period, the facility will be required to apply for a renewal of this operating permit, at which time the Department will evaluate the facility and issue a public notice with its findings.

VII. EXEMPT ACTIVITIES

The facility's operating permit does not include exempt activities such as office and interior maintenance activities, maintenance shop activities, food preparation facilities, cafeterias and dining rooms, etc. A complete list of exempt activities, as allowed by the Operating Permit rule, can be found at N.J.A.C. 7:27-22.1.

Table 1 - Operating Permit Revision History

| Permit Activity Number | Type of Revision | Description of Revision | Final Action Date |
|------------------------|--------------------------|--|-------------------|
| BOP190001 | Administrative Amendment | The Responsible official changed to Nellie D. Clark and contact information was updated in the Facility Profile. | 2/4/19 |
| BOP170002 | Minor Modification | <ul style="list-style-type: none"> - Added three new pieces of equipment including, a new slurry tank TM-1493, a new buffer tank TA-1520, and a new buffer tank TA-1536 (Equipment E1701 - E1703) to Batch Process BP2; - Added a new step to BP2-OS5 to indicate solids charging; - Increased the total number of batches processed annually for BP2 to 230 batches per year resulting in an annual VOC emissions increase from 3 tons/year to 6.70 tons/year; - Added two new 0.5 MMBtu/hr boilers (IS16 and IS17) to the insignificant source section of the permit; - Included Subchapter 6 TSP limit in BP2-OS9 and correct PM-10 and TSP emission limits, which are below reportable thresholds; and - Removed existing TA-1520 (Equipment # E233) tank from the permit. | 4/17/18 |
| BOP170001 | Administrative Amendment | The Responsible official changed from Todd Winge to Victor Cruz and contact information was updated in the Facility Profile. | 4/3/17 |

FACILITY NAME (FACILITY ID NUMBER)
BOP050001

Activity Number assigned by the Department

**New Jersey Department of Environmental Protection
Facility Specific Requirements**

Emission Unit Number assigned by the Facility

Brief description of emission unit

Emission Unit: U40 Sewage Sludge Incinerators
Operating Scenario: OS Summary

OR

OS2 Fluidized Bed Incinerator

OS Summary lists all rules and requirements that apply to an emission unit. An emission unit may contain one or more pieces of equipment and corresponding operating scenarios.

OSX denotes the operating scenario number and lists the rules and requirements that apply to a scenario. An operating scenario represents various ways (or scenarios) a piece of equipment is permitted to operate.

Item Number

Description of applicable requirement

Monitoring method to ensure compliance

Recordkeeping to show facility's compliance

Actions and submittals required for the facility

| Ref.# | Applicable Requirement | Monitoring Requirement | Recordkeeping Requirement | Submittal/Action Requirement |
|-------|---|--|--|--|
| 3 | The permittee shall conduct an annual performance test for each pollutant in Table 2 of 40CFR62 Subpart LLL between 11 and 13 calendar months after the previous performance test or within 60 days of a process change. [40 CFR 62.16000(a)] | Other: Conduct the performance test using the test methods, averaging methods and minimum sampling volumes or durations as specified in 40CFR62 Subpart LLL and according to the testing, monitoring and calibration requirements specified in 40 CFR 62.16015(a). [40 CFR 62.16000(a)]. | Other: (1) Maintain records of the results of initial, annual and any subsequent performance tests conducted to determine compliance with the emission limits and standards and/or to establish operating limits, as applicable. [40 CFR 62.16025(e)]. | Submit a report: Annually to the Administrator and to the Department. The permittee shall submit an annual compliance report as specified in 40 CFR 62. [40 CFR 62.16000(d)] |

Rule citation for applicable requirement

Rule citation for monitoring requirement

Rule citation for recordkeeping requirement

Rule citation for submittal/ action requirement

Explanation Sheet for Facility Specific Requirements